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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[30Day-16-0950]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

The National Health and Nutrition Examination Survey (NHANES), (OMB No. 0920-0950, expires 11/30/2016) - Revision - National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42

U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States.

The National Health and Nutrition Examination Surveys (NHANES) have been conducted periodically between 1970 and 1994, and continuously since 1999 by the National Center for Health Statistics, CDC. Annually, approximately 14,410 respondents participate in some aspect of the full survey. Up to 3,500 additional persons might participate in tests of procedures, special studies, or methodological studies (Table 1). Participation in NHANES is completely voluntary and confidential. A three-year approval is requested.

NHANES programs produce descriptive statistics which measure the health and nutrition status of the general population. Through the use of physical examinations, laboratory tests, and interviews NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States. NHANES monitors the prevalence of chronic conditions and risk factors. NHANES data are used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in

the health of the U.S. population over time. NCHS collects personal identification information. Participant level data items will include basic demographic information, name, address, social security number, Medicare number and participant health information to allow for linkages to other data sources such as the National Death Index and data from the Centers for Medicare and Medicaid Services (CMS).

A variety of agencies sponsor data collection components on NHANES. To keep burden down, NCHS cycles in and out various components. The 2015-2016 NHANES physical examination includes the following components: oral glucose tolerance test (ages 12 and older), anthropometry (all ages), 24-hour dietary recall (all ages), physician's examination (all ages, blood pressure is collected here), oral health examination (ages 1 and older), hearing (ages 20-59), dual X-ray absorptiometry (total body composition ages 6-59 and osteoporosis, vertebral fractures and aortic calcification ages 40 and older).

While at the examination center additional interview questions are asked (6 and older), a second 24-hour dietary recall (all ages) is scheduled to be conducted by phone 3-10 days later, and an appointment is made to return to the MEC to begin a 24-hour urine collection (one-half sample of ages 20-69). In 2014, a 24-hour urine collection was added to the NHANES protocol to better understand sodium intake and provide a

population baseline for use in monitoring trends in sodium intake in the future. In 2015, FDA is scheduled to implement a plan to promote broad, gradual reduction of added sodium in the food supply. One half of those successfully completing the initial collection will be asked to complete a second 24-hour urine. After completing the 24-hour urine participants are asked to provide 2 home urine collections (first morning and an evening) and mail them back. The urines collected in the morning and evening will be compared to the 24-hour urine collection.

NHANES also plans to conduct a waist circumference methodology study. The study population will be NHANES participants aged 20 and over who participate in the body measurements component in the Mobile Examination Center (MEC).

The bio-specimens collected for laboratory tests include urine, blood, vaginal and penile swabs, oral rinses and household water collection. Serum, plasma and urine specimens are stored for future testing if the participant consents.

The following major examination or laboratory items, that had been included in the 2013-2014 NHANES, were cycled out for NHANES 2015-2016: physical activity monitor, taste and smell component and upper body muscle strength (grip test).

Most sections of the NHANES interviews provide self-reported information to be used either in concert with specific examination or laboratory content, as independent prevalence

estimates, or as covariates in statistical analysis (e.g., socio-demographic characteristics). Some examples include alcohol, drug, and tobacco use, sexual behavior, prescription and aspirin use, and indicators of oral, bone, reproductive, and mental health. Several interview components support the nutrition monitoring objective of NHANES, including questions about food security and nutrition program participation, dietary supplement use, and weight history/self-image/related behavior.

NHANES data users include the U.S. Congress; numerous Federal agencies such as other branches of the Centers for Disease Control and Prevention, the National Institutes of Health, and the United States Department of Agriculture; private groups such as the American Heart Association; schools of public health; and private businesses. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Individuals in households	NHANES Questionnaire	14,410	1	2.5
Individuals in	Waist Circumference	3,000	1	8/60

households	Methodology Study			
Individuals in households	Special Studies	3,500	1	3

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